

REMARKS/ARGUMENTS

Obviousness-Type Double Patenting Rejection

Applicants have submitted an appropriate Terminal Disclaimer to overcome the Examiner's obviousness-type double patenting rejections. As such, Applicants respectfully request the Examiner's favorable consideration of the claims as presented.

Rejection of Claims 9-22 Under 35 U.S.C. §112 Second Paragraph

Applicants have amended Claims 9 and 11 and has adopted the Examiner's suggested language to place such claims for allowance (i.e., the phrase "a hormone conjugated with a toxin" has been employed in such claims). Moreover, the term "capable of" in Claims 9 and 22 has been modified pursuant to the Examiner's stated concerns by the deletion of such phrase. By such deletion, however, Applicants do not intend to narrow the claims in any manner and do not mean to change the scope of the presently claimed invention. Applicant believes that the term "capable of" would certainly be understood by one of ordinary skill in the art to adequately define the metes and bounds of the present invention. The referenced conjugate has the characteristic of being "capable of" selectively binding to a gonadotroph and capable of substantially precluding the gonadotroph from secreting gonadotrophins appear indefinite. Nevertheless, with the same intent, but only to address the Examiner's positive recitation with active verbs suggestion, Applicants have amended the claims in a manner to achieve favorable consideration.

With respect to Claim 9, the Examiner has indicated that the metes and bounds of the term "chemical toxin" is somehow unclear. Applicants respectfully disagree and believe that one of

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ordinary skill in the art would clearly understand what a “chemical toxin” comprises. Indeed, the specification refers, for example, to “chemical toxins selected from the group consisting of melphalan, methotrexate, nitrogen mustard, doxorubicin and daunomycin.” Moreover, further clarification of the term is found in the specification where it states that “obviously, a-chain and b-chain considerations will not be applicable to ‘chemical’ toxins because they are not made up of amino acid groups such as those found in bacterial or plant toxins.” In any event, Applicants respectfully submit that the above-referenced guidance provided by the specification fully informs one of ordinary skill in the art what the term “chemical toxin” refers to when used in the claims. Appropriate reconsideration and withdrawal of any rejection of Claim 9 on such basis is therefore requested.

With respect to Claim 13, Applicants have amended the same to recite “that inhibits protein biosynthesis”.

With respect to Claim 21, the Examiner questions what it means to “functionally inactivate cells.” In response, Applicants respectfully submit that as utilized in the specification, cells, and in particular, gonadotrophs, are inactivated by bioengineered proteins conjugated with GnRH. Such inactivation may be temporary and/or permanent, including the death of particular gonadotroph cells. Other uses of “inactivate” in the specification, refer to proteins which enzymatically inactivate mammalian ribozomes. Moreover, the term “inactivate” is also used in the context of inactivating endogenous LHRH in the circulation of an animal. In view of the appreciation by one of ordinary skill in the art that particular cells have certain functions, “functionally inactivate cells” is believed to be a term that is readily understood by one of skill in

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the art. As such, Applicants have not amended the claims, and submit that the present explanation, as well as that provided in the specification itself, is sufficient to obviate the Examiner's concerns.

Because Claims 10-12 and 14-20 are rejected only for depending on a rejected claim and in view of the above-referenced arguments and/or claim amendments, Applicants believe that all of such claims are now in a condition for allowance.

With respect to Claim 15, the Examiner objects to the claim language "and modified forms thereof", and as support for such concern, cites *University of California v. Eli Lilly & Co.* Applicants respectfully submit that the present claims do not present the concerns raised in the *University of California v. Eli Lilly & Co.* case because in that litigation, claims were directed to DNA that encoded insulin. Indeed, the Federal Circuit distinguished between chemical materials, as opposed to "claims to genetic material". Here, Claim 15 is particularly directed to single chain toxins selected from the group consisting of pokeweed anti-viral protein, alpha-amanitin, gelonin, ribozomin inhibiting protein (RIP), barley RIP, wheat RIP, corn RIP, rye RIP, flax RIP, "and modified forms thereof." One of ordinary skill in the art would certainly understand what modifications to the above-referenced specified toxin constituents can be arrived at. This is not a case, as presented in *University of California v. Eli Lilly & Co.*, where DNA was identified solely by its function. Given the numerous DNA molecules that could encode particular proteins having insulin functions, the Court was correct in questioning the use of such terminology. In the present case, however, such concerns are not raised given the clearly recited type of single chain toxins identified. In fact, the term "modified toxins" is defined in the specification and Table I provides

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representative examples of the same. Moreover, specific elimination of carboxy terminal binding portions of particular toxin chains is described as one of the modifications that can be made to a toxin. In short, Applicants submit that the Examiner's concerns about the present claim language in Claim 15 is not well founded and therefore Applicants respectfully request that the Examiner reconsider and allow Claim 15 as presently presented.

Applicants' counsel respectfully requests the courtesy of a telephone interview in the event the Examiner has any further questions or concerns regarding this matter. Applicants' counsel can be reached directly at (303) 863-2977.

Respectfully submitted,

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